

REMARKS

Entry of this Amendment and reconsideration of this application as amended are respectfully requested.

Claims 7-10, 12-14, 29 and new claims 31-42 are pending in this application. Claim 11 has been canceled and claims 1-6, 15-28 and 30, drawn to a non-elected embodiment, have been canceled without prejudice to filing a divisional application directed to the subject matter of these claims.

Claims 7-10, 12, 14 and 29 are amended. Unless an argument is made below directed to the novelty of each change to the claim in view of cited prior art, the changes to the claims do not relate to patentability.

Claim Objections

Claim 7 has been amended to remove the feature of the fluid being directed through the passage while the tube is situated over or along the guidewire so that claim 14 is no longer inconsistent with claim 7.

In view of the change to claim 7, it is respectfully submitted that the Examiner's objection to claim 14 has been overcome and should be removed.

Claim Rejections

Claims 7-11, 14 and 19 were rejected under 35 U.S.C. §102(b) as being anticipated by Hanson et al. (U.S. Pat. No. 5,709,874). Claims 12 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hanson et al. in view of Majlessi (U.S. Pat. No. 4,842,583).

Claim 7 has been amended and now recites a method for positioning a tube in the bowel including pushing a guidewire having a bulbous enlargement at a distal end into the body cavity, then facilitating passage of the guidewire through the bowel lumen by manipulating the bulbous enlargement, manipulation of the bulbous enlargement including applying, from a position alongside and exterior of the bowel, direct pressure against the bulbous enlargement or grasping the bulbous enlargement through intact overlying bowel wall, and then sliding the tube over or along the guidewire.

The application of direct pressure against the bulbous enlargement or grasping the bulbous

enlargement through intact overlying bowel wall is performed by a surgeon or other personnel in the operating room. Thus, the surgeon assists in the passage of the guidewire through the bowel lumen by pressing or grasping the bulbous enlargement of the guidewire directly through the bowel wall, typically from a position alongside and exterior of the bowel, and then once the guidewire is in position, positioning the tube by passing it over the guidewire. In other words, the surgeon may advance the guidewire through the bowel lumen until the bulbous enlargement reaches a desired position in the bowel by manually grasping or manipulating the bulbous enlargement through intact overlying bowel wall and urging the bulbous enlargement forward through the bowel lumen to the desired position (as now set forth in new claim 34).

Hanson et al. and Majlessi do not disclose, teach or suggest facilitating passage of a guidewire through the bowel lumen by manipulating the bulbous enlargement by applying, from a position alongside and exterior of the bowel, direct pressure against the bulbous enlargement or grasping the bulbous enlargement through intact overlying bowel wall.

In Hanson et al., the “manipulation” of the bulbous enlargement mentioned at col. 6, lines 33-37 relates to the provision of an angle between the tip 30 of the guidewire relative to the longitudinal axis of the tube 12 to enable the tip 30 to direct the device into a branch or bifurcation of an artery or vein. There is absolutely no application of direct pressure against the bulbous enlargement from a position alongside and exterior of the body conduit, or grasping the bulbous enlargement through an intact overlying wall of the body conduit. Rather, Hanson et al. discloses guiding the bulbous tip at the distal end by manipulating the proximal end of the guidewire, as is often done in vascular catheterizations.

In Majlessi, there is an irrigating device 10 with an irrigating tube 12 having an enlarged distal end 26 and the irrigating tube 12 is not movable relative to any guidewire, i.e., the irrigating tube 12 is not slid over or along a guidewire. Also, there is no application of direct pressure against a bulbous enlargement of a guidewire or grasping of a bulbous enlargement of a guidewire through intact overlying bowel wall.

Furthermore, it would not have been obvious to modify Hanson et al. in view of Majlessi as suggested by the Examiner because Majlessi does not teach that a guidewire with a bulbous enlargement can be passed into a bowel lumen, and once in place, facilitate passage of a tube over the guidewire. The irrigating device 10 of Majlessi is designed to be passed through the bowel and

the relatively wide diameter of the shaft of the tube (in comparison to the width of a guidewire) required to accomplish irrigation and aspiration, impedes the passage of the irrigating device 10 through the bowel.

By contrast, the separate guidewire and tube in accordance with the present invention takes advantage of a thin, flexible or resilient wire (which provides less drag and resistance to passage through the bowel than a wider shaft of an irrigating tube as in Majlessi, yet is stiff enough so that the guidewire can also be effectively pushed from behind) attached to a bulbous head or enlargement. This combination can be passed quickly into and through the bowel and allows passage through a tortuous bowel that would prohibit the passage of a fluid-conveying tube, even one with a bulbous enlargement, such as disclosed in Majlessi.

Moreover, the Examiner's position that it "would be obvious to combine Hanson and Majlessi because Majlessi discloses a guidewire and irrigation tube in one piece Hanson is an obvious variant in that in Hanson the guidewire and irrigation tube are separate pieces. It has been held that constructing a former integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 170" is respectfully traversed on the grounds that Majlessi does not disclose a guidewire and irrigation tube in one piece. That is, the irrigating device 10 of Majlessi is capable of guiding itself through the bowel but does not incorporate a wire that is used for this purpose, i.e., a flexible rod. One skilled in the art would therefore not combine a method of passing and manipulating an integral tube with a bulbous enlargement near its end (Majlessi) with a method of pushing a guidewire, and then a tube over the guidewire (Hanson et al.) and thus would not arrive at the present claimed invention.

In view of the foregoing, it is respectfully submitted that the Examiner's rejections of the claims 7-10, 12-14 and 30 have been overcome and should be removed.

New Claims

Claims 31-42 are added and all are directed to the elected embodiment. Claims 31-33 depend directly or indirectly from claim 7. Claim 34 is a new independent claim that includes the features of pushing a guidewire having a flexible shaft and a bulbous enlargement at a distal end of the shaft into the bowel, the bulbous enlargement having a diameter of about 0.25 inches to about 0.75 inches and a smooth outer arcuate surface, and then from a position alongside and exterior of the bowel,

advancing the guidewire through the bowel lumen until the bulbous enlargement reaches a desired position in the bowel by manually grasping or manipulating the bulbous enlargement through intact overlying bowel wall and urging the bulbous enlargement forward through the bowel lumen to the desired position. The prior art cited by the Examiner does not disclose, teach or suggest these features. Claims 35-42 depend from claim 34 and set forth features similar to those set forth in dependent claims 8-10, 12-14 and 29.

No fee is due for the presentation of claims 31-42 in view of the cancellation of claims 1-6, 15-28 and 30.

Interview Request

After consideration of this Amendment, the Examiner is respectfully requested to contact the undersigned if any issues remain that can be resolved telephonically to place the application into condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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